

Notice of Allowability

Application No.

09/836,804

Examiner

Shaojia A. Jiang

Applicant(s)

MESFIN ET AL.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to August 13, 2004.
2. ☒ The allowed claim(s) is/are 7-11 (now remunerated to 1-5).
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

SAJ 10/26/04
SHAOJIA ANNA JIANG
PATENT EXAMINER

DETAILED ACTION

Applicant's amendment and remarks submitted August 13, 2004 are acknowledged wherein claims 1-6 are cancelled; claims 7-12 have been amended.

As pointed out in the previous Office Action, acknowledgment is made of applicant's claim priority to provisional application Serial No. 60/198,688 filed April 20, 2000.

The reasons for allowance and Examiner's Amendment as follows.

Examiner's Amendment

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Ms. Lucy X. Yang on October 19, 2004.

Claims has been amended as follows:

- In claim **7**, inserting the phrase “**wherein said mammal is not suffering from a bacterial infection**”, after “...mammal in need thereof” and before “comprising....”.
- canceling claim **12**.

Reasons For Allowance

Currently, claims 7-11 are pending in this application.

Claims 7-11 have been examined on the merits herein.

The claimed method for treating osteoporosis or bone resorption in a vertebrate mammal in need thereof wherein said mammal is not suffering from a bacterial infection comprising administering to the mammal an effective amount of a compound of formula II, is not seen to be taught or fairly suggested by the prior art, as discussed below.

Applicant's remarks submitted August 13, 2004 with respect to the rejection of claims 6 and 12 made under 35 U.S.C. 112, first paragraph, as containing new matter, for the negative limitation, "said mammal is not suffering from a bacterial infection", of record stated in the Office Action dated February 17, 2004 have been considered and found persuasive to remove this particular rejection since this limitation is supported in claims 6 and 12 as originally filed. Therefore, the said rejection is withdrawn.

Examiner's Amendment set forth above which limits the vertebrate mammal patients to those who are not suffering from a bacterial infection in need of treating osteoporosis or bone resorption in the claimed method, is sufficient to overcome the rejection made under 35 U.S.C. 103(a) as being unpatentable over Hester et al. (WO 9854161) in view of Nair et al., and the rejection made under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (WO 9912914) in view of Nair et al. of record in the Office Action dated June 18, 2003, since the instant vertebrate mammal patients who are not suffering from a bacterial infection in need of treating osteoporosis or bone resorption in the claimed method, are deemed to be separate and patentably distinct

from the patients who have bone destruction and/or osteoporosis maybe caused by bacterial infections in view of the cited prior art. Moreover, it is deemed not obvious to one of ordinary skill in the art that employing an antibacterial agent for treating osteoporosis or bone resorption in a patient who has no bacterial infection.

Thus, the claimed method herein is not seen to be anticipated by the prior art under 35 U.S.C. 102 based on an inherency rationale, or to be obvious over the same reference under 35 U.S.C. 103(a).

Moreover, the instant specification is seen to provide the enabling information to practice invention herein for a method for treating osteoporosis or bone resorption in a vertebrate mammal in need thereof by administering the instant compound to the mammal without undue experimentation. For example, the specification shows the factual evidence of the *vivo* studies as working examples by administering the instant compound to rats (see page 44-45 of the specification). Thus, the specification is deemed to provide sufficient support and enablement for the claimed invention herein.

Accordingly, Applicant's amendment and remarks submitted August 13, 2004, accompanying the Examiner's amendment are sufficient to remove all rejections made in the prior Office Action as discussed above and place the application in condition for allowance.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is 571.272.0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on 571.272.0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.
Primary Examiner, AU 1617
October 26, 2004